

REMARKS

Entry of the foregoing amendments and reexamination and reconsideration of the above-captioned application, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested. The examiner has noted certain informalities with regard to the use of genus and species names in certain of claims 22-28. Applicant hereby proffers the necessary correction. In addition, the examiner has rejected claim 13 pursuant to 35 U.S.C. § 112, second paragraph as being indefinite or redundant. Applicant agrees that the claim is redundant and has therefore canceled claim 13 without prejudice or disclaimer.

Claims 11-28 are rejected as being allegedly obvious over U.S. Patent No. 4,396,631 ("the '631 patent") when taken in view of U.S. Patent No. 5,422,346 ("the '346 patent"), U.S. Patent No. 5,531,989 ("the '989 patent"), U.S. Patent No. 5,527,556 ("the '556 patent"), and U.S. Patent No. 4,021,545 ("the '545 patent"). Applicant respectfully traverses. It is clear from the official action that the examiner has engaged in a hindsight reconstruction of applicant's invention using applicant's patent as a template or road map from which to pick and choose the necessary elements from other prior art. It is not enough to merely find all of the elements of a claimed invention in numerous patents and, without more, suggest that their combination renders the claims obvious. But, that is exactly what the Patent Office has done here.

The examiner first cites the '631 patent stating that it teaches a method of producing tablets with live bacteria comprising the steps of mixing live bacteria with starch or other suitable materials and pressing the mixture into tablets. The tablets allegedly retain high viability of the lactic acid bacteria after tablet formation and during storage. The examiner acknowledges that the cited method is lacking in a disclosure of the essential use of a fructose oligosaccharide or inulin.

With all due respect to the Patent Office, however, this rejection is essentially equivalent to a contention that the reference teaches everything but the invention. The specification of the instant application teaches that starch can be used as well as conventional tableting excipients. However, starch alone is clearly not enough to obtain the results in accordance with the present invention. Moreover, as the '631 patent teaches in col. 3, lns. 28-32, the starch described and claimed therein exerts its influence whether tablets are formed or not. According to example 1 of the '631 patent, starch is a good preservative. However, in accordance with the present invention, fructose oligosaccharide such as inulin is useful in protecting the integrity of the bacteria during tablet formation. Its preservative effects, if any, are secondary.

The differences between the claimed invention and the disclosure of the '631 patent, however, are far more numerous than mere differences in the materials used, even if that is the most prominent difference. The objectives of the two references, and the ways in which those objectives are met, are completely different. Nothing in the '631 patent teaches or suggests that fructose oligosaccharides, such as inulin, could be used in forming a tablet, could be used in forming a tablet with live bacteria, could be used in forming a tablet while maintaining a high viability of live bacteria, or even that such materials are equivalent to starch in any way, let alone in the context of the presently claimed invention. Indeed, the only evidence of record, namely that found in the specification of the present application, suggests that starch and fructose oligosaccharides are, in the context of the present invention, not equivalent, as the present invention will work without starch but not without fructose oligosaccharides.

None of the secondary references supply the teachings which are deficient from the '631 reference. The '346 patent, for example, allegedly teaches the use of a fructose oligosaccharide or inulin in a method of producing tablets.

However, there the similarity ends. The '346 patent does not appear to teach or suggest the formation of a tablet which contains both a fructose oligosaccharide such as inulin and bacteria. All that the '346 patent teaches is that fructose oligosaccharide, and more particularly juices containing a specific content of certain fructose oligosaccharides, even when reduced to powdered form, can have a certain value when given an individual. They note that these oligosaccharides are growth promoting substrates for lactic bacteria. But that is a reference to promoting the already existing bacteria in the gut of the patient. The fructose oligosaccharide is not used in any method for introducing non-native or exogenous bacteria at all. It therefore cannot teach or suggest that fructose oligosaccharides would play any role to ensure the viability of a bacteria during tablet formation. For that reason, the '346 patent is completely deficient in terms of both teaching the present invention and supplying that which is missing from the '631 patent discussed above.

The examiner also cited the '989 patent as allegedly teaching a method of producing a dry mixture of 40-60% by weight of inulin and a lactic bacteria. However, noticeably absent from the examiner's characterization of the '989 patent is a description of its formation of tablets by compression. In fact, at col. 13, lns. 38-58, the '989 patent describes that its preferred method of administering the formulation described is in a powder, and that no tableting procedures are taught or suggested. Thus, this reference cannot be said to legitimately teach that fructose oligosaccharides would be useful in producing tablets containing live bacteria, nor could it possibly teach that the use of these materials, as opposed to others, can be in any way beneficial in maintaining the viability of live bacteria during tablet formation.

The '556 patent allegedly teaches producing a semi-solid inulin product with live lactic bacteria in the form of a cream. The cream can also, allegedly, be used to form a tablet. It is apparent that this allegation is based on an unsupportive reasoning. Example 13 of the '556 patent, which

deals with a yogurt (a product normally containing bacteria) was cited as showing that it is possible to mix an inulin cream with bacteria. The examiner then cites example 16, which allegedly suggests the creation of a chocolate which can be made in "tablets" as part of a confection. In truth, the reference to the "tablet" here is quite clearly different from that used in the sense of a pharmaceutical product. In any event, the '556 patent does not teach the possibility of forming a solid material from a mixture containing both inulin and a live bacteria. In fact, as the examples cited by the examiner demonstrate, it actually teaches just the opposite. It teaches the possibility of making formulations, such as creams, containing lactic acid and inulin. It never suggests that tablets could be made with both of their components. Moreover, it certainly teaches nothing about the advantages which inure from the use of inulin as a tableting aid. In fact, it never even teaches the use of compression to form a tablet.

Finally, the examiner cites the '545 patent as allegedly teaching a method of producing tablets comprising inulin or other additives, such as starch or calcium diphosphate. Applicant has never disputed that inulin could be used as a tableting aid. But that does not mean that anyone prior to the present inventors actually recognized its properties in terms of maximizing the viability of live bacteria in bacterial containing tablets. Nothing in the '545 patent would provide that teaching. Indeed, if anything, the '545 patent would suggest that all of its mentioned ingredients are equally useful as tableting aids, something which applicant has discovered is not true when dealing with bacterial containing formulations.

For all the foregoing reasons, even if the various cited references were combinable, something that has not been established on the record, they nevertheless could still not teach the presently claimed invention, namely protecting the viability of live bacteria in tablets by the use of a fructose oligosaccharide such as inulin. As such, the examiner has

failed to carry her burden of establishing a *prime facie* case of obviousness. Accordingly, the rejection should be withdrawn.

Should the examiner have any questions with regard to the foregoing, she should contact the undersigned, at her convenience, at (908) 654-5000 in order to overcome any additional objections which she might have.

If there are any additional charges in connection with this requested amendment, the examiner is hereby authorized to charge Deposit Account No. 12-1095 therefor.

Applicant requests a face-to-face or telephone interview once the examiner has taken up this case.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is earnestly solicited.

Respectfully submitted,

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